PATENT

AF/STFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

L E T T E R

Applicant: Roger P. Jackson

Serial No.: 10/783,889 Date: January 19, 2010

Filed: February 20, 2004 Group Art Unit: 3733

Exam: David C. Comstock

For: ANTI-SPLAY MEDICAL IMPLANT CLOSURE WITH MULTI-SURFACE REMOVAL APERTURE

- -

Kansas City, Missouri

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed herewith is a replacement brief in accordance with the requirement dated September 16, 2009.

The fee for filing the brief has already been paid. Consequently, no additional fee is believed due at this time. If an additional fee is found to be due, please charge it to deposit account No. 50-1253.

Respectfully Submitted,

Roger P. Jackson

By: 
John C. McMahon
Reg. No. 29,415
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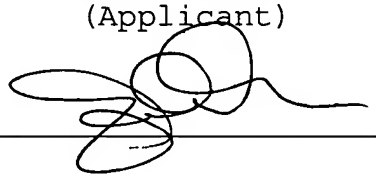
Roger P. Jackson
(Applicant)

By 

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Kansas City, Missouri

Appeal No._____

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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

ATTENTION: Board of Patent Appeals and Interferences

APPELLANT'S BRIEF

This brief is filed in support of the Notice of Appeal in this application which was mailed on December 1, 2008.

The fees required under 41.2(b)(2) are submitted herewith.

TABLE OF CONTENTS

I REAL PARTY IN INTEREST

The applicant Roger P. Jackson is the real party in interest.

II RELATED APPEALS AND INTERFERENCES

The following is a related patent application on appeal to the Board of Appeals:

Serial No. 10/784,066 for which a Notice of Appeal was filed concurrently with the Notice of Appeal for this application.

III STATUS OF THE CLAIMS

Claims cancelled:	1 to 20
Claims pending:	21 to 23
Claims rejected:	21 to 23
Claims allowed:	none
Claims appealed:	21 to 23

IIIa JURISDICTIONAL STATEMENT

This appeal is an appeal from a Patent Office action under 35 U.S.C. 134(a).

The Office action appealed from was mailed September 16, 2008. Several actions during the pendency of this application have been "Final" including the action of September 16, 2008.

The Notice of Appeal was filed December 1, 2008.

The Appeal Brief was filed May 1, 2009 in conjunction with a Request for Extension of Time until May 1, 2009 and is refiled January 19, 2010 to make corrections required on September 19, 2009 with an Extension of Time.

IV STATUS OF AMENDMENTS

There are no outstanding or pending amendments.

V Summary of Claimed Subject Matter

Claim 21 is directed to the combination of a bone implant screw {8, page 17, line 18 to page 21, line 11, and see Figs. 6-8} adapted for connection to a bone fixation structural member {10, page 17, line 20 to page 21, line 11, and see Figs. 6-8} and a closure {1, page 15, line 22 to page 22, line 13, and see Figs. 1-9} for setting engagement with the structural member; said closure comprising a substantially cylindrical body {4, page 18, line 9} having an outer cylindrical surface {4, page 18, line 9} relative to a central closure axis {25, page 18, line 10}; a substantially continuous guide and advancement flange {35, page 19, line 6 to page 20, line 8} extending helically about the outer cylindrical surface and being sized and shaped to interlock with a mating guide and advancement flange {22, page 18, line 1 to page 20, line 8} on a receiving structure {8, page 17, line 22 to page 18, line 4, and see Fig. 8}; the flange {35, page 19, line 6 to page 20, line 8} having a leading surface {37, page 18, lines 9-11} and a trailing surface {28, page 18, lines 9-11} relative to a direction of forward advancement; at least one of the leading surface and the trailing surface being compound in contour and including an inward facing anti-splay surface component {37, page 19, line 10 to page 20, line 8} facing generally toward said closure axis; the body having a multi-surface aperture {2, page 21, line 12 to page 22, line 13, and

see Figs. 3-5 and 9} formed therein that is aligned with the closure axis {25, page 22, lines 10-11, and see Fig. 5} and that is elongated along the closure axis {25, page 22, lines 10-11, and see Figs. 5 and 8}, the aperture opening onto a trailing surface {28, see Figs. 8-9} of the body and including a plurality of circumferentially spaced, centrally facing surfaces {45, 47, page 21, line 16 to page 22, line 13} extending substantially parallel to the closure axis that are aligned to form a removal socket adapted to receive a removal tool {not shown, page 21, lines 19-23}; a break off installation head {6, page 18, line 11 to page 19, line 5}; the bone screw comprising a threaded shank {14, page 17, lines 22-23, and see Figs. 6-7} adapted for threaded implanting into a bone; an open head {16, page 17, line 23 to page 18, line 4, and see Fig. 8} formed by a pair of spaced apart arms {18, page 17, line 24 to page 18, line 4, and see Fig. 8} having mutually facing channel surfaces defining a structural member receiving channel {20, page 17, line 24 to page 18, line 4, and see Fig. 8} to receive a bone fixation structural member {10, page 18, line 1 and page 20, lines 9-18}; the mutually facing channel surfaces having respective mating guide and advancement structures {22, page 18, lines 1-4, page 19, lines 10-14, and see Fig. 8} formed therein which are compatible with and rotatably mateable with the guide and advancement flange {page 19, lines 8-20, and see Fig. 8} to enable guiding and

advancement of the body into the channel to thereby clamp the bone fixation structural member therein and to interlock the body and arms; and further wherein the mating guide and advancement structures of said bone implant screw each includes an outward anti-splay surface component which cooperates with the inward anti-splay surface component of the closure in such a manner as to resist a tendency of the arms to splay in reaction to torquing the closure into engagement with said bone fixation structural member {page 19, lines 8-20, page 20, lines 5-8, and see Fig. 8}; the guide and advancement flange has a relatively enlarged region near an outer periphery thereof that forms the inward anti-splay surface component {35, 37, page 19, lines 10-14}; the mating guide and advancement structures are contoured in a complementary manner to the guide and advancement flange to form the outward anti-splay surface component {22, 39, page 19, lines 10-14}; and the inward anti-splay surface component engages the outward anti-splay surface component when the closure is guided and advanced into the open screw head of the bone implant screw so as to interlock said body to the arms to resist radially outward splaying movement of the arms {page 19, lines 14-20}.

Claim 22 is directed to a combination of a bone implant screw {8, page 17, line 18 to page 21, line 11, and see Figs. 6-8} adapted for connection to a bone fixation structural member

{10, page 17, line 20 to page 21, line 11, and see Figs. 6-8} and a closure {1, page 15, line 22 to page 22, line 13, and see Figs. 1-9} for setting engagement with the structural member; the closure comprising a substantially cylindrical body {4, page 18, line 9} having an outer cylindrical surface {4, page 18, line 9} relative to a central closure axis {25, page 18, line 10}; a guide and advancement flange {35, page 19, line 6 to page 20, line 8} extending helically about the outer cylindrical surface; the guide and advancement flange being sized and shaped to interlock with a mating guide and advancement flange {22, page 18, line 1 to page 20, line 8} on a receiving bone screw {8, page 17, line 22 to page 18, line 4, and see Fig. 8}; the flange having a trailing surface relative to the forward advancement direction; the trailing surface being compound in contour and including an inward facing anti-splay surface component {37, page 19, line 10 to page 20, line 8} facing generally toward the closure axis; the body having a multi-lobular aperture {2, page 21, line 12 to page 22, line 13, and see Figs. 3-5 and 9} formed therein which is aligned on and elongated along the closure axis {25, page 22, lines 10-11, and see Fig. 5}, the aperture including a plurality of circumferentially spaced lobes {45, page 21, line 16 to page 22, line 13} extending substantially parallel to the closure axis and the lobes circumferentially alternating with bore grooves {47, page 21, line 16 to page 22, line 13} extending substantially parallel to the closure axis to form a

removal socket adapted to receive a removal tool {not shown, page 21, lines 19-23}; a break off installation head {6, page 18, line 11 to page 19, line 5}; the bone screw comprising a threaded shank {14, page 17, lines 22-23, and see Figs. 6-7} adapted for threaded implanting into a bone; an open head {16, page 17, line 23 to page 18, line 4, and see Fig. 8} formed by a pair of spaced apart arms {18, page 17, line 24 to page 18, line 4, and see Fig. 8} having mutually facing channel surfaces defining a structural member receiving channel {20, page 17, line 24 to page 18, line 4, and see Fig. 8} to receive a bone fixation structural member {10, page 18, line 1 and page 20, lines 9-18}; the mutually facing channel surfaces each having an internal mating guide and advancement structure {22, page 18, lines 1-4, page 19, lines 10-14, and see Fig. 8} formed therein which is compatible for slidably mating with the flange {page 19, lines 8-20, and see Fig. 8} upon rotation of the body to enable advancement of the body into the channel to thereby clamp the bone fixation structural member therein and to interlock the body to the arms to resist splaying of the arms {page 19, lines 8-20, page 20, lines 5-8, and see Fig. 8}; and further wherein the mating guide and advancement structures of the bone implant screw each includes an outward anti-splay surface component which cooperate with the inward anti-splay surface component of the flange in such a manner as to resist splaying of the arms {page 19, lines 8-20, page 20, lines 5-8, and see Fig. 8}; the flange has a

relatively enlarged region near an outer periphery thereof that forms the inward anti-splay surface component {35, 37, page 19, lines 10-14}; the mating guide and advancement structures are contoured in a complementary manner to said flange to form said outward anti-splay surface component {35, 22, page 19, lines 8-20}; and the inward anti-splay surface component engages the outward anti-splay surface component when the closure is rotated into the open screw head of the bone implant screw {37, 39, page 19, lines 14-20}.

Claim 23 is directed to a combination of a bone implant screw {8, page 17, line 19 to page 21, line 11, and see Figs. 6-8} adapted for connection to a bone fixation structural member {10, page 17, line 20 to page 21, line 11, and see Figs. 6-8} and a closure {1, page 15, line 22 to page 22, line 13, and see Figs. 1-9} for setting engagement with the structural member; the closure including a substantially cylindrical body having an outer cylindrical surface relative to a central closure axis {25, page 21, line 13, and see Figs. 5 and 8}, the improvement comprising the closure having a flange {35, page 19, line 6 to page 20, line 8} that has a leading surface and a trailing surface with at least one of the leading surface {37, page 18, lines 9-11} and said trailing surface being compound in contour so as to form a substantially continuous guide and advancement flange {35, page 19, line 6 to page 20, line 8} extending

helically about the outer surface and including an inward facing anti-splay surface component {37, page 19, line 10 to page 20, line 8} facing generally toward the closure axis; the flange being sized and shaped to interlock with a mating guide and advancement flange {22, page 19, lines 8-20} on a receiving structure {arms 18, page 19, lines 17-20}; the body having a multi-surfaced aperture {2, page 21, line 12 to page 22, line 13, and see Figs. 3-5 and 9} formed therein which is located and elongated along the closure axis {25, page 22, lines 10-11, and see Fig. 5}, the aperture including a plurality of circumferentially spaced surfaces {45, 47, page 21, line 16 to page 22, line 13} extending substantially parallel to the closure axis so as to form a removal socket adapted to receive a removal tool {not shown, page 21, lines 19-23}; a break off installation head {6, page 18, line 11 to page 19, line 5}; and the bone screw comprising a threaded shank {14, page 17, lines 22-23} adapted for threaded implanting into a bone; an open head {16, page 17, line 23 to page 18, line 4, and see Fig. 8} formed by a pair of spaced apart arms {18, page 17, line 24 to page 18, line 4, and see Fig. 8} having mutually facing channel surfaces defining a structural member receiving channel {20, page 17, line 24 to page 18, line 4, and see Fig. 8} to receive a bone fixation structural member {10, page 18, line 1 and page 20, lines 9-18}; the mutually facing channel surfaces having respective mating guide and advancement structures {22, page 18, lines 1-4, page 19,

lines 10-14, and see Fig. 8} formed therein which are compatible to allow rotational mating with the guide and advancement flange {page 19, lines 8-20, and see Fig. 8} to enable guiding and advancement of the body into the channel to thereby clamp the bone fixation structural member therein and to interlock the arms to the body to resist splaying of the arms; the mating guide and advancement structures of the bone implant screw each including an outward anti-splay surface component which cooperates with the inward anti-splay surface component of the flange in such a manner as to resist a tendency of the arms to splay in reaction to torquing and other forces {page 19, lines 8-20, page 20, lines 5-8, and see Fig. 8}; the guide and advancement flange having a relatively enlarged region near an outer periphery thereof that forms the inward anti-splay surface component {35, 37, page 19, lines 10-14}; the mating guide and advancement structures being contoured in a complementary manner to the guide and advancement flange to form the outward anti-splay surface component {22, 39, page 19, lines 10-14}; and the inward anti-splay surface component engaging the outward anti-splay surface component when the closure is guided and advanced into the open screw head of the bone implant screw so as to radially interlock {page 19, lines 14-20}.

VI GROUNDS OF REJECTION TO BE REVIEWED

1) Are claims 21-23 properly rejected under 35 U.S.C. 102(b) as being anticipated by Shafer (DE29810798U1)?

2) Are claims 21-23 properly rejected under 35 U.S.C. 102(b) as being anticipated by Morrison (6,292,642)?

VII ARGUMENT

BACKGROUND SUPPORT FOR ARGUMENT

Applicant is an orthopedic surgeon specializing in spinal surgery. He works daily with implanting spinal implants of the type found in the present application. He has also worked extensively with manufacturing companies that produce spinal implants both in designing entire product lines and individual implants.

Prior to the filing of the filing of the present application, Dr. Jackson recognized that there was an inherent problem with open headed bone screws of the type used in spinal surgeries. In particular, such bone screws have a receiver or head with a pair of spaced upstanding arms that form a rod receiving channel between them. The implants are quite small with a receiver that is only slightly bigger than a pencil eraser. Perhaps the most significant problem with such open headed bone screws is that the arms are relatively small and cannot withstand much outward directed force, otherwise the arms

will splay or spread which can lead to catastrophic failure of the implant, because an associated closure and rod become loose in the receiver after which the rod moves relative to the receiver.

One type of closure is illustrated in the Puno Patent No. 5,474,555 and provides an outer nut that goes entirely around the arms that holds the arms to keep them from splaying. However, there are several problems with the Puno nut. In particular, there is little space within which to work around the receiver along the rod. Such space is often referred to as the "run on the rod". The Puno nut significantly increases the space taken up by the bone screw along the run on the rod making it unusable in some situations. Furthermore, the nut is large and heavy. Both of these factors make the outer nut undesirable.

Other inventors, including applicant, have developed closures that slide sideways into slots in the receiver. These do not require rotation; however, such closures are hard to use in minimally invasive surgery and require a second structure, such as a set screw, for locking the rod relative to the receiver.

Other inventors have tried to use a threaded plug for the closure that uses a conventional V-thread and is threadably received between the arms. The problem with a V-thread type plug where the sides of the thread are, for example, at a 45° angle with respect to the base is that the torque needed to tighten the

closure against the rod to lock the rod in place produces splaying of the arms. This is because the surfaces of such a thread cause approximately half of the downward force to be exerted axially and half radially outward. Because the closures must be set with a high torque for such a small device (normally about 100 inch pounds), the outward force can push the walls so as to splay them.

An inventor by the name of Metz-Stavenhagen suggested using buttress threads where, in theory, all of the forces should be exerted axially. Applicant and others, have also shown in patent applications and used helically wound reverse angle threads on the closure. Reverse angle threads should, in theory, actually pull the arms radially inward toward the closure. While buttress and reverse angle V-threads perform better than threads where the sides are both at acute angles relative to the base, all V-threads still have an inherent problem. In particular, so much force is applied in torquing the closure and the threads are so thin that the threads can bend. As the threads are essentially smooth on both sides, after bending, they can radially slide relative to each other under torquing which leads to splaying.

One further method has been developed to prevent splaying. This involves a closure with one or more flanges that extend radially outward and are received in similar shaped receivers in the arms. These distinguish from the closures noted above that slide in sideways in that they are rotated, twisted or screwed

approximately one fourth revolution to seat in the receiver. Applicant is of the opinion that the cited Schafer reference (German 298 10 798) also shows such a structure which will be discussed more extensively in the argument's section. There are a number of problems with such devices. In particular, such closures must be pushed down against the rod until the flanges on the closure align with the flange receivers on the arms and then rotated until the two parts join which typically requires a 90° rotation, twist or screwing of the closure. During assembly, the closure of such devices can not be advanced in a helically wound path under the guidance of the receiver, so such closures are difficult to install and typically another device such as a set screw received in an axially aligned bore or the like must be used to lock the rod.

Applicant has developed a helically wound closure with a radially interlocking structure between the closure and the arms of the receiver that resists splaying of the arms even at a high setting torque and that requires no other structure, such as a set screw, to lock the rod in place. The high torque ensures that the rod will not slip or move relative to the receiver which can seriously compromise the value of the implant and could cripple the patient.

Argument with respect to rejection of Claims 21 to 23 as anticipated by Schafer (DE 2810798)

Schafer Rejection

The pending claims were rejected as anticipated by Schafer (German 298 10 798). The cited Schafer patent is directed to two different embodiments. The first embodiment is a closure of the type with a reverse angle thread. The reverse angle thread of Fig. 1 is a V-thread with smooth sides which can bend and radially slide relative to a mating thread and is urged to not in any way show or describe the radially interlocking structures between the closure body and arms as is called for in applicant's claims. More importantly, the first embodiment is not shown or described as being helically wound. It is described as being screwed in; however, the term screw can mean simple rotation into something. It is believed that the first embodiment of Schafer is a push down and twist structure like the second embodiment and as discussed below. This interpretation is supported by the Schafer specification and is consistent with other devices that Schafer patented and produced.

The second cited embodiment of Schafer is shown in Fig. 2. This embodiment was apparently added as a quick after thought, is poorly described, and includes only a partial cross section of the receiver in Fig. 2 and a single paragraph describing the embodiment of Fig. 2. The last Office Action cites the paragraph describing Fig. 2 as follows:

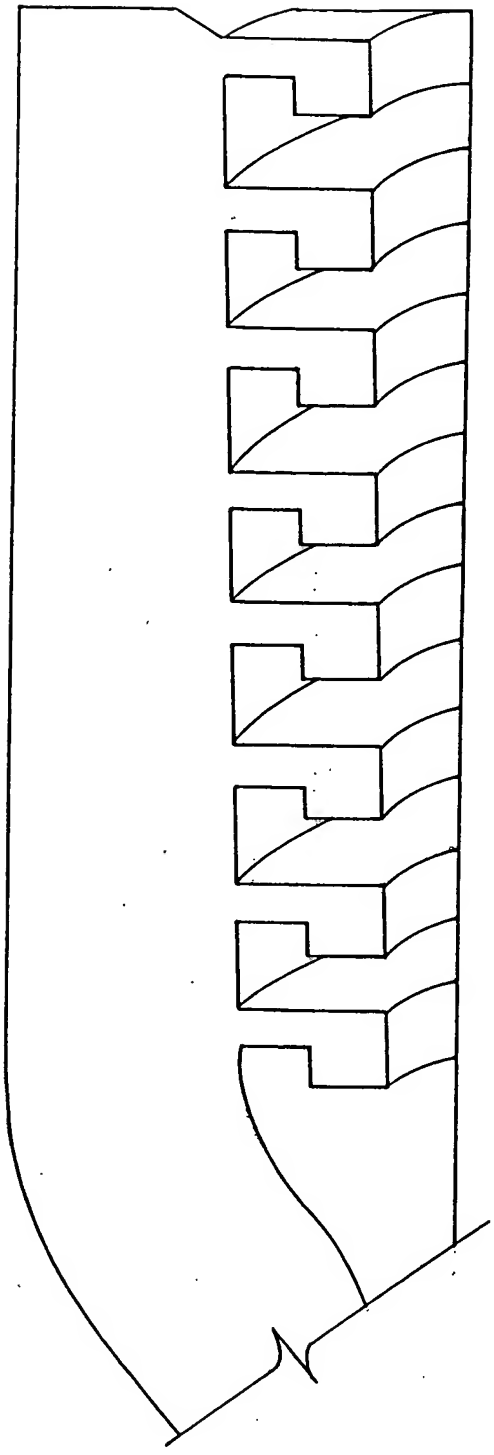
> "In the exemplary embodiment shown in Figure 2, the bifurcated head 4 of the bone screw 1 likewise has a

thread, which, however, has a top flank 11 and a bottom flank 10 embodied in a stepped fashion. The shoulder of the bottom flank 10 is shaped such that it forms an undercut 17. This undercut 17, particularly by means of the shoulder 18, prevents the legs 5 from being bent radially outward while the **grub screw** 3 is being **screwed in**. A positive lock is thus produced in the radial direction between the bifurcated head 4 and grub screw 3. This positive lock prevents, as previously mentioned, any slippage of the leg 5." (Emphasis added by the Office action).

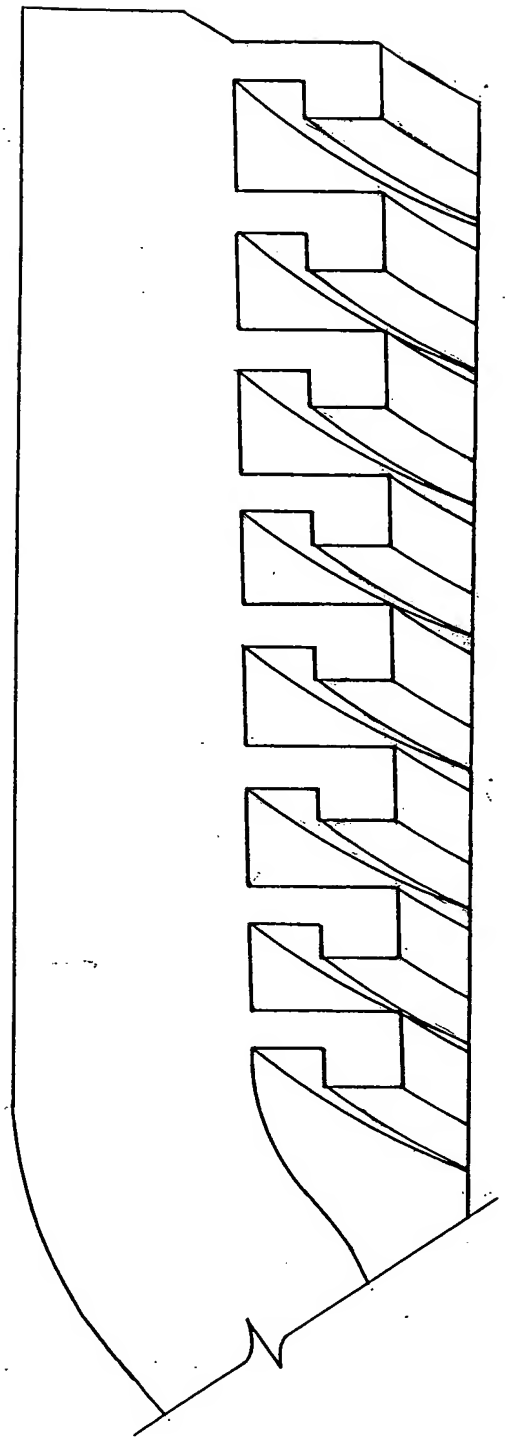
The Office action argues that this paragraph and Fig. 2 clearly show and describe a helically wound structure of the type claimed by applicant. Applicant respectfully disagrees.

In particular, the cited Schafer device does not show a helically wound pitch and further, one must take the disclosure of Schafer in light of what was known to one having ordinary skill in the art at the priority date of the present application. The art of this invention is quite complex, but no one had previously shown an interlocking structure that was helically wound. When reviewing the Schafer patent, as one having skill in the art at the priority date would have done, an engineer or other skilled person would look to see what Schafer actually teaches. The second embodiment of Schafer neither shows or teaches a closure, so a closure must be somehow imagined to work

with the receiver of Fig. 2. In studying the disclosed Schafer receiver to see how to make a closure, it is clear that all of the tiers of structure (seven complete in total) are equally spaced from the bottom of the channel on both the front and back sides of each tier, as shown in the drawing. Consequently, it is impossible for the tiers to have a pitch and, likewise, it is impossible for such tiers to be helically wound. To be helically wound each tier must have such a pitch to go from one tier to the next with each 360 degree revolution of the tier. Further, in Fig. 2 each tier would have to slope downward toward the rear and in Schafer Fig. 2 each tier is essentially horizontal. On the following page is a representation on the left that is Fig. 2 of the Schafer reference and a representation on the right that is of a structure modified with respect to Schafer, if Schafer were modified to be helically wound.



SCHAFER
FIG. 2



SCHAFER MODIFIED TO BE HELICALLY WOUND CONSISTENT WITH APPLICANT'S INVENTION

It is apparent from reviewing these two images that one having skill in the art would immediately see that the device of Fig. 2 of Schafer is not helically wound and that is was of the type of closure wherein the mating structure on the closure was not helically wound, but rather the closure and receiver were aligned by pushing down and then the closure was designed to be screwed in by twisting or rotating 90° to secure the parts together.

The geometry of applicant's device is quite complex because a compound and complicated surface is being helically wound about the closure and a like structure is being wound about the inside of the arms. It is urged that at the time of filing, it was not apparent to one having skill in the art that such a complex structure could be made or that it could work upon rotation during assembly. Perhaps even more important is that the Schafer structure does not suggest that one having ordinary skill in the art should even look at or try to make a helically wound device. It is noted that machine shops were unable to manufacture applicant's device for many years because of the great complexity, even after applicant told them what he wanted. The Office action points out that the short disclosure in Schafer indicates that there is a thread and that a grub screw is screwed into it. A closure of the push and twist type, described above, is clearly not helically wound. In addition, it is noted that a structure that mates upon rotating 90° can be called a grub screw

and rotation or twisting can be interpreted and translated from the German into English as being "screwed in" in the Schafer disclosure to distinguish from the closures that are slid in sideways without rotating. Consequently, it is believed that applicant's interpretation of Schafer is completely consistent with the written description, especially as it would be interpreted by one with skill in the art at the time. The drawing of Schafer would either teach one to make a non helically wound device or, alternatively, fails to teach how to make any effective device.

It is further noted that Schafer was a well known German inventor who had many U.S. patents. It is interesting to review these patents because of what his later patents show. Schafer's 289 10 798 German patent has publication and other dates in the late 1990's. Nevertheless, when he designed the later closures, he used the "push down to align and then twist 90°" structure that is urged to be shown in the earlier patent rather than a helical wound structure. For example, the following views are from his US 6,340,749 patent that was filed in 2002.

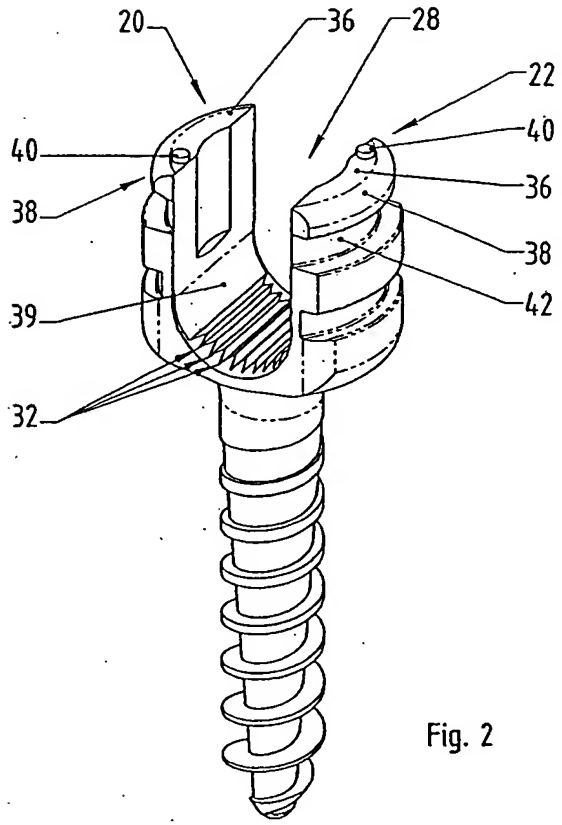


Fig. 2

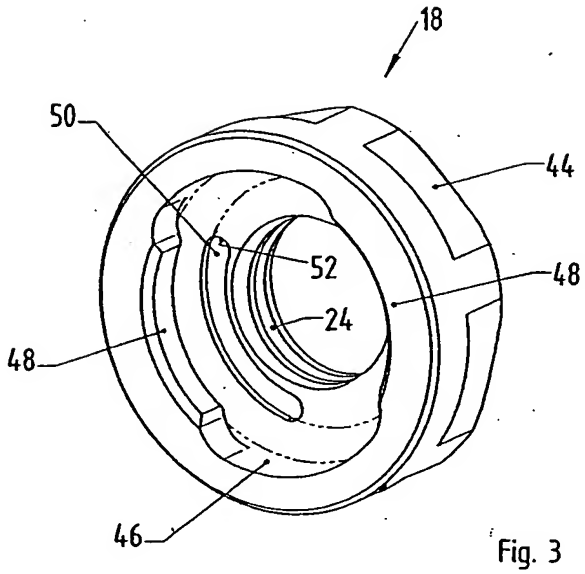


Fig. 3

The structure shown in the 6,540,749 patent clearly has an "push down and align and then twist 90°" closure (nut 18) that mates with a receiver (head 16) having receiving structure. If Schafer had conceived of the helically wound structure earlier, why did he use the "align and twist" structure rather than the preferable helically wound structure that does not require an additional locking screw (26)? The answer is that Schafer had

not envisioned such technology and that anyone of ordinary skill in the art who reviewed Schafer's patent, also would not envision such technology based upon his teachings. Persons trying to better understand the poorly presented Schafer reference that was cited may look to his later patents and see the "align and twist" type closure, as is found in Patent No. 6,540,749. Consequently, it is urged that Schafer fails to anticipate the pending claims for the noted reasons. In particular, Schafer does not teach a closure with a helical wound and radially interlocking guide and advancement structure. Furthermore, Schafer does not teach or show a break-off head and cannot anticipate the claims for this reason also. It is also urged that Schafer fails to in anyway suggest or teach applicant's claimed invention to one having ordinary skill in the art.

Argument with respect to rejection of Claims 21 to 23 as anticipated by Morrison (6,292,642)

Morrison Rejection

The pending Claims are rejected as anticipated by Morrison, et al. (6,296,642). While Morrison, et al. teaches a closure with a helically wound thread, it is a simple V-thread of the reverse angle type which has been discussed above with respect to Schafer and other art, including applicant's own closure with a reverse angle thread.

Nothing in Morrison, et al. in any way shows, suggests or teaches providing a closure that has structure which radially

interlocks with the receiver arms. Consequently, for the same reasons as were discussed with respect to Schafer, it is urged that Morrison, et al. does not anticipate applicant's claimed structure. Further, Morrison, et al. does not suggest that a radially interlocking structure can be or should be made.

In summary, it is urged that neither Schafer nor Morrison anticipate applicant's invention as called for in the claims.

VIII CLAIMS APPENDIX

A. PENDING CLAIMS

Claims 1 to 20 (Canceled)

Claim 21 In combination a bone implant screw adapted for connection to a bone fixation structural member and a closure for setting engagement with the structural member; said closure comprising:

(a) a substantially cylindrical body having an outer cylindrical surface relative to a central closure axis;

(b) a substantially continuous guide and advancement flange extending helically about said outer cylindrical surface and being sized and shaped to interlock with a mating guide and advancement flange on a receiving structure; said flange having a leading surface and a trailing surface relative to a direction of forward advancement;

(c) at least one of said leading surface and said trailing surface being compound in contour and including an inward facing anti-splay surface component facing generally toward said closure axis;

(d) said body having a multi-surface aperture formed therein that is aligned with said closure axis and that

is elongated along said closure axis, said aperture opening onto a trailing surface of said body and including a plurality of circumferentially spaced, centrally facing surfaces extending substantially parallel to said closure axis that are aligned to form a removal socket adapted to receive a removal tool;

(e) a break off installation head; said bone screw comprising:

(f) a threaded shank adapted for threaded implanting into a bone;

(g) an open head formed by a pair of spaced apart arms having mutually facing channel surfaces defining a structural member receiving channel to receive a bone fixation structural member;

(h) said mutually facing channel surfaces having respective mating guide and advancement structures formed therein which are compatible with and rotatably mateable with said guide and advancement flange to enable guiding and advancement of said body into said channel to thereby clamp said bone fixation structural member therein and to interlock said body and arms; and further wherein:

(i) said mating guide and advancement structures of said bone implant screw each includes an outward anti-splay surface component which cooperates with said inward anti-splay surface component of said closure in such a

manner as to resist a tendency of said arms to splay in reaction to torquing said closure into engagement with said bone fixation structural member;

(j) said guide and advancement flange has a relatively enlarged region near an outer periphery thereof that forms said inward anti-splay surface component;

(k) said mating guide and advancement structures are contoured in a complementary manner to said guide and advancement flange to form said outward anti-splay surface component; and

(l) said inward anti-splay surface component engages said outward anti-splay surface component when said closure is guided and advanced into said open screw head of said bone implant screw so as to interlock said body to said arms to resist radially outward splaying movement of said arms.

Claim 22 The combination of a bone implant screw adapted for connection to a bone fixation structural member and a closure for setting engagement with the structural member; said closure comprising:

(a) a substantially cylindrical body having an outer cylindrical surface relative to a central closure axis;

(b) a guide and advancement flange extending helically about said outer cylindrical surface; said guide and

advancement flange being sized and shaped to interlock with a mating guide and advancement flange on a receiving bone screw; said flange having a trailing surface relative to said forward advancement direction;

(c) said trailing surface being compound in contour and including an inward facing anti-splay surface component facing generally toward said closure axis;

(d) said body having a multi-lobular aperture formed therein which is aligned on and elongated along said closure axis, said aperture including a plurality of circumferentially spaced lobes extending substantially parallel to said closure axis and said lobes circumferentially alternating with bore grooves extending substantially parallel to said closure axis to form a removal socket adapted to receive a removal tool;

(e) a break off installation head; said bone screw comprising:

(f) a threaded shank adapted for threaded implanting into a bone;

(g) an open head formed by a pair of spaced apart arms having mutually facing channel surfaces defining a structural member receiving channel to receive a bone fixation structural member;

(h) said mutually facing channel surfaces each having an

internal mating guide and advancement structure formed therein which is compatible for slidably mating with said flange upon rotation of said body to enable advancement of said body into said channel to thereby clamp said bone fixation structural member therein and to interlock said body to said arms to resist splaying of said arms; and further wherein:

(i) said mating guide and advancement structures of said bone implant screw each includes an outward anti-splay surface component which cooperate with said inward anti-splay surface component of said flange in such a manner as to resist splaying of said arms;

(j) said flange has a relatively enlarged region near an outer periphery thereof that forms said inward anti-splay surface component;

(k) said mating guide and advancement structures are contoured in a complementary manner to said flange to form said outward anti-splay surface component; and

(l) said inward anti-splay surface component engages said outward anti-splay surface component when said closure is rotated into said open screw head of said bone implant screw.

Claim 23 A combination of a bone implant screw adapted for connection to a bone fixation structural member and a closure for

setting engagement with the structural member; said closure including a substantially cylindrical body having an outer cylindrical surface relative to a central closure axis, the improvement comprising:

(a) said closure having a flange that has a leading surface and a trailing surface with at least one of said leading surface and said trailing surface being compound in contour so as to form a substantially continuous guide and advancement flange extending helically about said outer surface and including an inward facing anti-splay surface component facing generally toward said closure axis; said flange being sized and shaped to interlock with a mating guide and advancement flange on a receiving structure;

(b) said body having a multi-surfaced aperture formed therein which is located and elongated along said closure axis, said aperture including a plurality of circumferentially spaced surfaces extending substantially parallel to said closure axis so as to form a removal socket adapted to receive a removal tool;

(c) a break off installation head; and said bone screw comprising:

(d) a threaded shank adapted for threaded implanting into a bone;

(e) an open head formed by a pair of spaced apart arms having mutually facing channel surfaces defining a structural member receiving channel to receive a bone fixation structural member;

(f) said mutually facing channel surfaces having respective mating guide and advancement structures formed therein which are compatible to allow rotational mating with said guide and advancement flange to enable guiding and advancement of said body into said channel to thereby clamp said bone fixation structural member therein and to interlock said arms to said body to resist splaying of said arms;

(g) said mating guide and advancement structures of said bone implant screw each including an outward anti-splay surface component which cooperates with said inward anti-splay surface component of said flange in such a manner as to resist a tendency of said arms to splay in reaction to torquing and other forces;

(h) said guide and advancement flange having a relatively enlarged region near an outer periphery thereof that forms said inward anti-splay surface component;

(i) said mating guide and advancement structures being contoured in a complementary manner to said guide and advancement flange to form said outward anti-splay surface component; and

(j) said inward anti-splay surface component engaging said outward anti-splay surface component when said closure is guided and advanced into said open screw head of said bone implant screw so as to radially interlock.

IX EVIDENCE APPENDIX

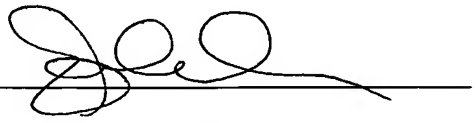
NONE

X RELATED PROCEEDINGS APPENDIX

NONE

Respectfully submitted,

Roger P. Jackson

BY: 

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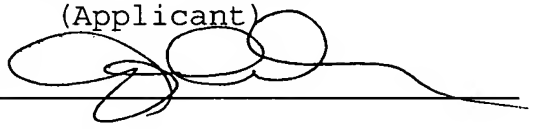
(Applicant)

By 

January 19, 2010

(Date of Signature)